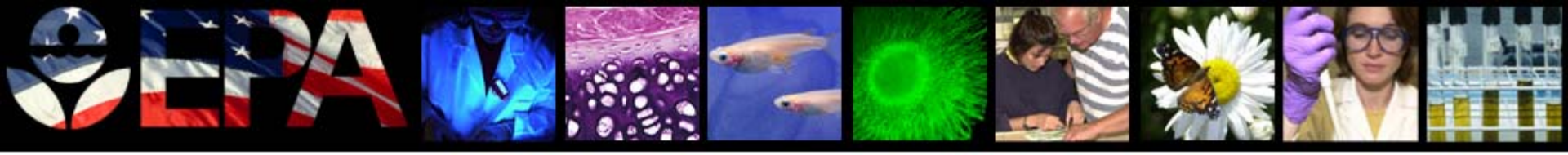
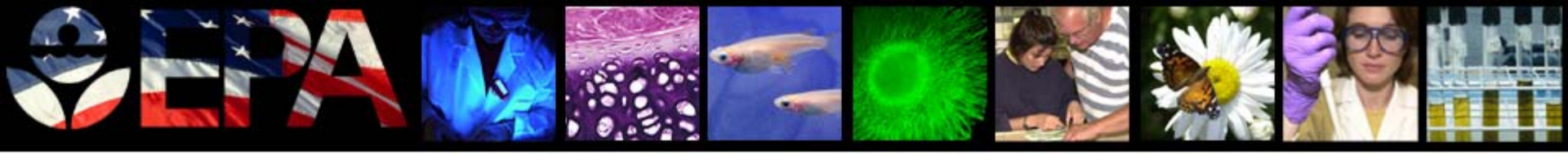


Update on Activities of EPA Genomics Task Force

Kerry Dearfield & Bill Benson

U. S. Environmental Protection Agency

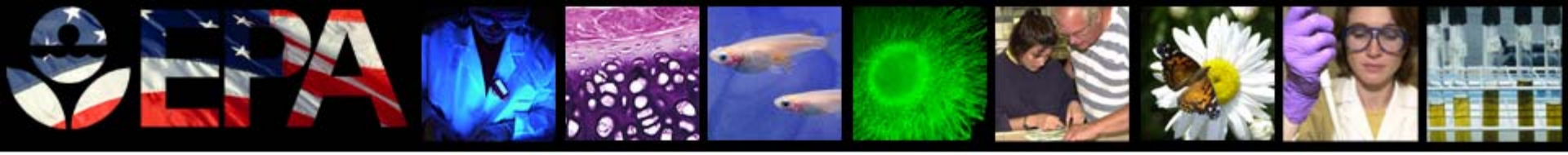
Presentation to EPA Computational Toxicology Workshop
September 30, 2003



Science Policy for Genomics

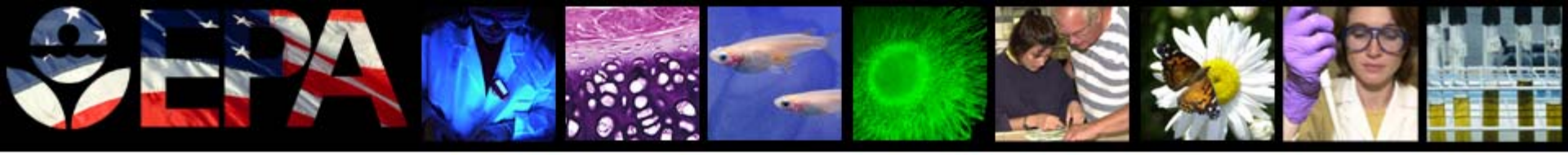
In early 2002, the Science Policy Council (SPC) charged an Agency Action Plan Work Group to:

- Develop an Interim Genomics Policy
- Develop an Action Plan to address technical and policy challenges for appropriate use of genomics technologies and data in EPA



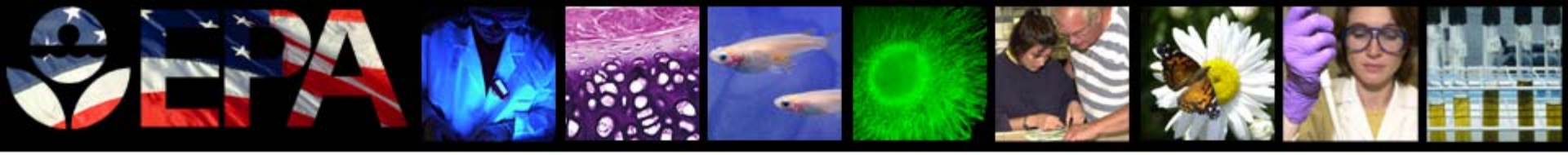
Interim Policy on Genomics 1

- June 25, 2002, Interim Policy issued
- http://www.epa.gov/osp/spc/genomics.htm
- EPA encourages and supports continued genomics research as a powerful tool for understanding the molecular basis of toxicity and developing biomarkers of exposure, effects, and susceptibility



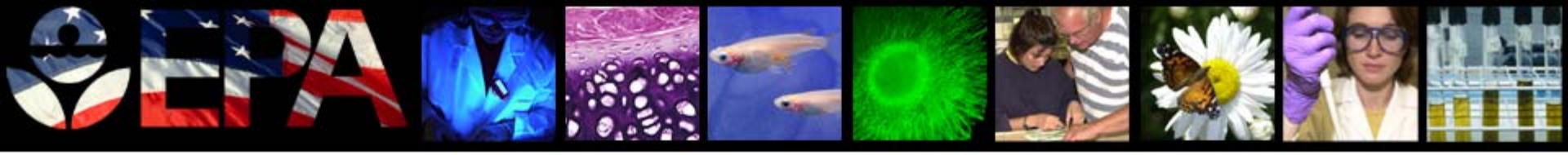
Interim Policy on Genomics 2

- Genomics data alone are currently insufficient as a basis for risk assessment and management decisions
- Limited use while Agency gain experience in assessing the quality, accuracy, and reproducibility and relevance of the data
- May be useful in a weight-of-evidence approach for human health and ecological risk assessments



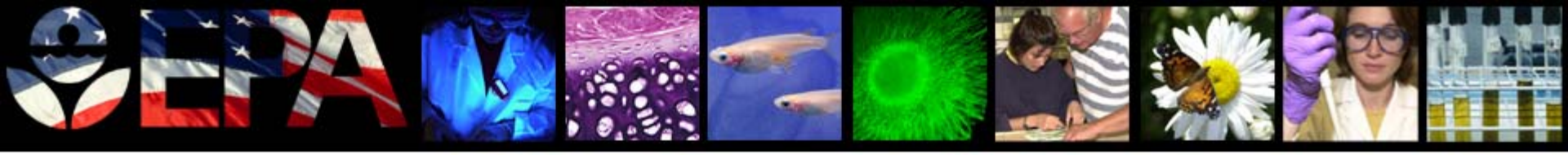
Action Plan: Issues to Consider 1

- http://intranet.epa.gov/ospintra/scipol/action.htm
- Scientific Research: Computational Toxicology
- Methods/Data Management: standardization of methods and databases, bioinformatics, QA
- Ethical, Legal, Social Implications: Ensuring privacy and fairness in the use and interpretation of genetic information including responsible use and integration of genetic technology in research



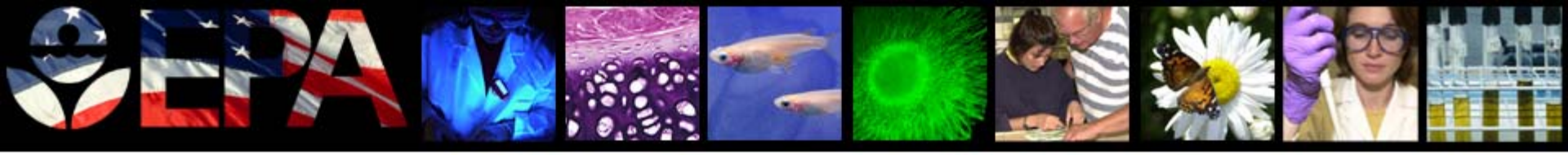
Action Plan: Issues to Consider 2

- Risk Assessment: Explore ways to incorporate genomic information into Agency risk assessments, refine risk assessment guidelines
- Training: Develop a coordinated genomics education agenda
- Communication: Effectively distribute genomic science and policy decisions internally and externally



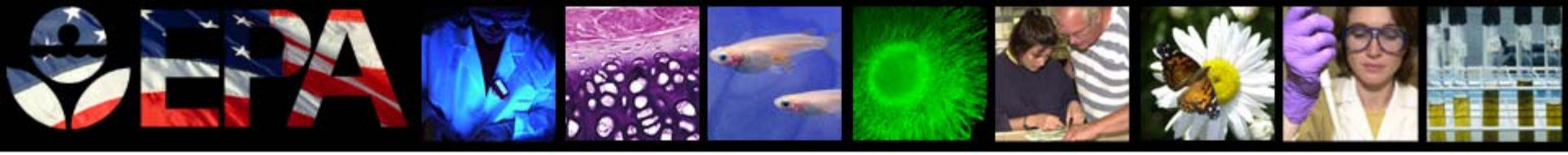
Genomics Action Plan: Progress 1

- Genomics Short-Term Implementation Workgroup convened by Paul Gilman
  - Charged SAB to form Bioethics Panel to serve as Agency resource
    - Genomics
    - Human Subject Testing
    - Animal Welfare
  - Charged formation of Genomics Task Force



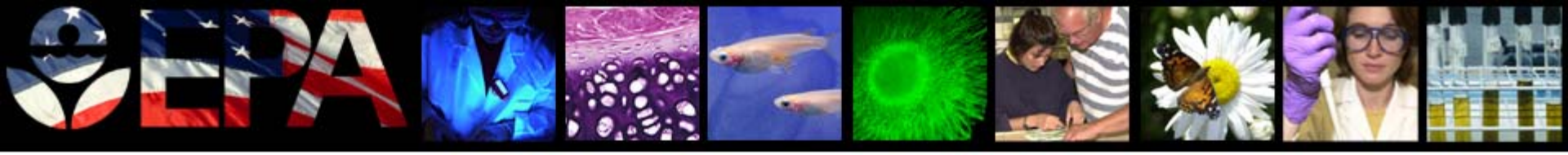
Genomics Task Force

- Larry Reiter & Vanessa Vu – Agency co-chairs for SPC
- Bill Benson & Kerry Dearfield – working workgroup chairs
- Representatives from across Agency program, regional, and research offices



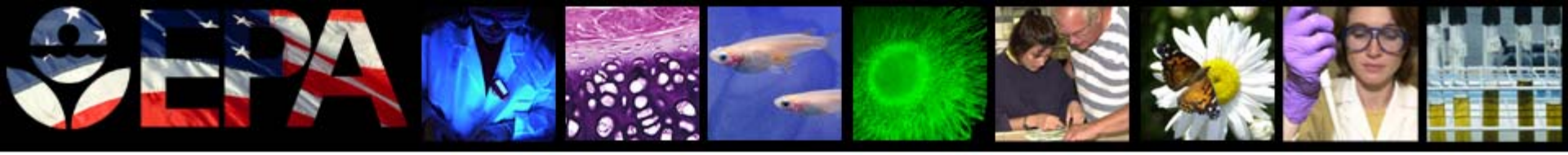
Genomics Task Force Charge

- Develop an Agency White Paper
  - Identify anticipated regulatory scenarios and implications for use of genomics
  - Inventory of Agency science activities that may support the regulatory scenarios – where is this going and what is needed
  - Identify gaps/science needs



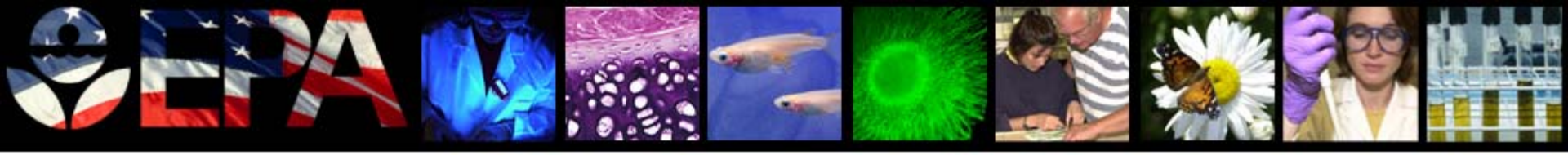
Identified Regulatory Scenarios 1

- Prioritization: for screening purposes, for testing purposes, for making a decision
  - Group a chemical with a class that may require testing or not
  - Improving predictive capability of traditional SAR approaches



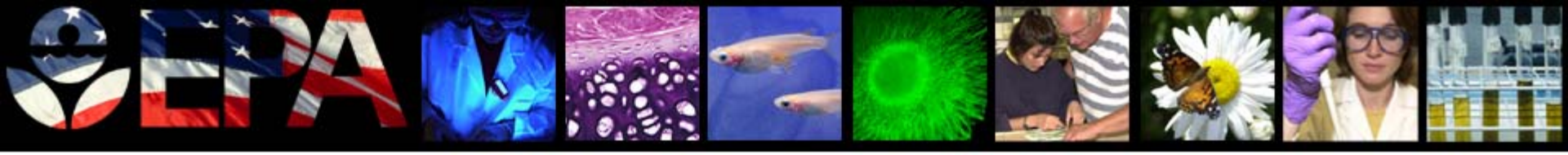
Identified Regulatory Scenarios 2

- Monitoring: for determining the state of the environment, site-specific or media-specific data
  - Assessment and compliance purposes
  - Evaluate status and trends of various environmental indicators



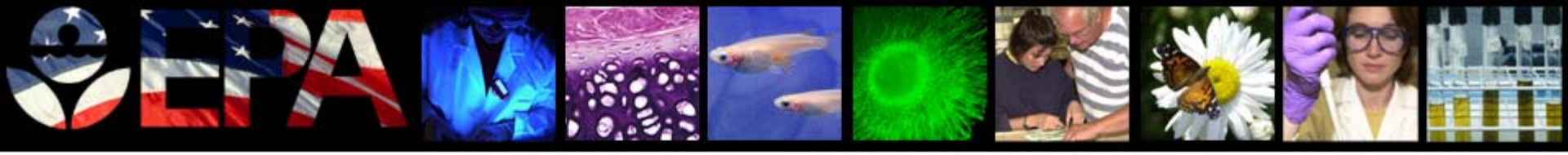
Identified Regulatory Scenarios 3

- Health assessments: improve the quality of these assessments
  - Identify possible mode(s) of action
  - Identify possible LOAEL/NOAEL
  - Use in cumulative risk – determine common mode(s) of action
  - Identify possible sensitive populations



Identified Regulatory Scenarios 4

- Reporting: how genomics information triggers reporting requirements, right-to-know provisions
  - Adverse effects by chemicals, stressors; e.g. TSCA 8(e), FIFRA 6(a)(2)
  - Toxics Release Inventory (TRI)



The End

Thank you very much